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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,045	05/12/2000	SE-JIN LEE	JHU1440-1	1418

28213 7590 05/19/2003

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/19/2003

*22*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/485,045

Applicant(s)

LEE ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-42,53-55 is/are pending in the application.
- 4a) Of the above claim(s) 1,12-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4-11 and 53-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 24 February 2003 is acknowledged. Claims 1, 2, 4-42, and 53-55 are pending in this Application. Claims 1 and 12-42 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections Withdrawn***

2. The rejection of claims 43 and 47-53 under 35 U.S.C. 112, first paragraph, as lacking written description and enablement is withdrawn in response to Applicant's cancellation of these claims.

3. The rejection of claims 43 and 47-52 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's cancellation of these claims.

#### ***Claim Rejections Maintained***

4. The rejection of claims 2, 4-11, and 53-55 under 35 U.S.C. 101 is maintained for reasons of record on pp. 2-4 of the office action of paper no. 20.

Applicant argues that the specification teaches that GDF-16 can have growth and differentiation activity and can be used as a marker for a cell proliferative disorder. Applicant further argues that GDF-16 can be used for diagnosing and treating a cell proliferative disorder. Applicant additionally argues that the related protein TGF $\beta$ -4 has utility in diagnosing cancer.

Applicant's arguments have been fully considered but have not been found persuasive. As stated in the office action of paper no. 20, there is no activity known to be associated with the encoded protein. There are no diseases known to be associated with the protein and no diseases for which its presence is known to be diagnostic. Thus there is no "specific benefit in currently

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available form" associated with the protein and thus with the encoding polynucleotide.

Applicant does not identify or confirm a "real world" context of use; clearly further research would be required to identify a disease or function associated with this protein and thus endow the encoding polynucleotides with a utility.

*See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals,

'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.'

That the polynucleotide is homologous with TGF $\beta$ -4 also does not serve to endow it with a utility. The '751 patent discloses that TGF $\beta$ -4 can be used to identify cancer cells but does not teach any function for this protein. Sequence similarity may provide guidance as to function but does not indicate that genes are similarly expressed; gene expression is not controlled by the protein-encoding region. Thus similarity in this region does not indicate that there is any similarity in expression and the homology to TGF $\beta$ -4 does not indicate that GDF-16 can be used to identify cancer cells. Since the '751 patent does not disclose any activity for TGF $\beta$ -4, the homology between GDF-16 and TGF $\beta$ -4 does not imply any activity for GDF-16.

5. The rejection of claims 2, 4-11, and 53-55 under 35 U.S.C. 112, first paragraph, as lacking enablement because there is no associated utility is maintained for reasons of record on p. 4 in the office action of paper no. 20. Since, for the reasons set forth above and on pp. 2-4 of the previous office action, there is no utility associated with the polynucleotides, one of skill in the art would not know how to use it.

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NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.


Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
May 6, 2003

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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